K073296

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN - 9 2008

Submitter

Company: ..... 3M ESPE AG
Street: ..... ESPE Platz
ZIP-Code, City: ..... D-82229 Seefeld
Federal State: ..... Bavaria
Country: ..... Germany
Establishment Registration Number 9611385
Official Correspondent: ..... Dr. Andreas Petermann,
..... Manager Regulatory Affairs
Phone: 011-49-8152-700 1395
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E-mail: ..... Andreas.Petermann@mmm.com
Date: ..... November 16, 2007

Name of Device

Proprietary Name: TempXN28

Classification Name: ..... Temporary Crown and Bridge Resin

Common Name: ..... Composite based Temporary Crown and Bridge Material

Predicate Device

Protemp™ 3 Garant™ by 3M ESPE K033022
Luxatemp Fluorescence by DMG USA, Inc. K013674
Sinfony by 3M ESPE K992645

Description for the Premarket Notification

TempXN28 is a temporary crown and bridge resin intended to make a temporary prosthesis, such as a crown or bridge, for use until a permanent restoration is fabricated. Temporary crown and bridge resin is designated at 21 C.F.R § 872.3770 as a Class II device.

Like Protemp™ 3 Garant™, TempXN28 is available in the proven Garant™ mixing and dispensing system.

To provide evidence for safety biocompatibility testing was carried out. The results show that TempXN28 is a safe device.

The comparison for chemistry, performance data and indications for use shows that TempXN28 is substantially equivalent to the predicate devices.

In summary, it can be concluded that safety and effectiveness requirements for TempXN28 are completely met.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 9 2008

Dr. Andreas Petermann
Manager, Regulatory Affairs
3M ESPE AG Dental Products
ESPE Platz
Seefeld, Bavaria,
GERMANY D-82229

Re: K073296
Trade/Device Name: Temp XN28
Regulation Number: 21 CFR 872.3770
Regulation Name: Temporary Crown and Bridge Resin
Regulatory Class: II
Product Code: EBG
Dated: November 16, 2007
Received: November 23, 2007

Dear Dr. Petermann:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

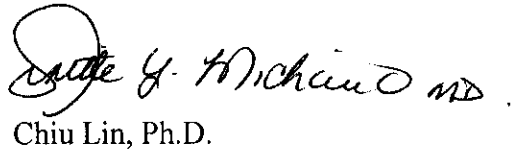
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K073296

Device Name: TempXN28

Indications For Use: Fabrication of temporary crowns, bridges, inlays, onlays and veneers.
Fabrication of long-lasting temporary restorations.
Lining material for prefabricated temporary crowns made of composite and metal.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner
(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices
510(k) Number K073296